

A return to pith and marrow? The UK Supreme Court comes full circle

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By Gregory Bacon

Yes, you read that right. Thirteen years after the House of Lords had firmly shut the door on any notion of a doctrine extending the scope of patent protection outside the claims, the UK Supreme Court in yesterday's judgment in *Actavis v Eli Lilly* [2017] UKSC 48 reversed gear and reintroduced a true form of doctrine of equivalents into UK law. The judgment comes as a surprise, as the previously established UK case law had over time firmly done away with the idea of 'pith and marrow' infringement, culminating in the seminal House of Lords judgment in *Kirin-Amgen v Hoechst Marion Roussel* [2004] UKHL 46. In that case Lord Hoffmann had explained that the correct approach to claim construction was to abandon literalism in favour of purposive construction and that Article 69 EPC prevented equivalence from extending protection outside the claims even if it could be used to construe the scope of those claims under purposive construction. We had previously reported the result as this was announced last week, and have now had time to digest the reasons, which are summarised below.

Background

The claims at issue were to use of a composition comprising pemetrexed disodium and vitamin B12 for treatment of tumour growth, albeit as either Swiss-type or EPC 2000 claims. In its multiple DNI actions, Actavis had sought to argue that its generic pemetrexed / vitamin B12 products did not infringe on the basis that they contained either pemetrexed diacid, pemetrexed dipotassium or pemetrexed ditromethamine but not the disodium salt. The Courts at first instance and on appeal had held that Actavis did not directly infringe the claims as the claims in question were limited to the disodium salt, albeit that the Court of Appeal had overturned the Patents Court's finding on indirect infringement in holding that these products infringed when reconstituted in saline for injection as pemetrexed disodium was formed from the pemetrexed anion and the sodium cation in solution.

Doctrine of equivalents

The Supreme Court's decision turned on the question of whether a variant could be held to infringe a patent claim. In doing so, the Court decided the role of equivalence in determining the scope of protection. Relying on the approach in other European countries, the Supreme Court (with Lord Neuberger giving judgment on behalf of the Court) decided that Lord Hoffmann's approach to the issue in *Kirin-Amgen* was not entirely correct. In the Court's opinion, the question of infringement in a case of variants was best addressed by addressing two issues: (i) does the variant infringe any of the claims as a matter of normal interpretation?; and, if not (ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? This approach was held to comply with Article 2 of the Protocol on Article 69 as issue (ii) raises the principle of equivalents, but limits its ambit to those variants which contain immaterial variations from the invention. The Court was of the view the Lord Hoffmann in *Kirin-Amgen* had erred by conflating these two issues into a single question of interpretation.

In determining the answer to the first question, the applicable principles were clear and followed those of construction of documents generally (including contracts). On that basis, Actavis' products did not directly infringe as in no sensible way could Actavis' products be said to fall within the expression "pemetrexed disodium". However, that was not the end of the matter as in order to give fair protection to the patentee the Court still had to ask whether those products were an immaterial variant of the construed claims.

The Protocol questions

In deciding whether a variant was immaterial, the Supreme Court revisited the 'Improver' or 'Protocol questions'. Importantly, the Court reformulated the second of these questions as in its view the second question had been improperly applied previously and by the Courts below (albeit when considering the Protocol questions in the context of purposive construction). It is worth setting out the reformulated questions below:

i) *Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?*

ii) *Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?*

iii) *Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?*

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no".

The significant change with this reformulation is that it introduces hindsight into the determination of the second question, as the skilled person is now assumed to know that the variant achieves substantially the same result as the invention and the patentee is not required to demonstrate this in the patent or on the basis of the skilled person's common general knowledge. The Supreme Court came to this conclusion on the basis that the previous incarnation of the second Protocol question imposed too high a burden on the patentee as it required the skilled person to work out for themselves whether the variant would work. That had an impact on the facts of the case before the Court, as it had been held that although the skilled person would not know which other pemetrexed salts would have acceptable properties for use in the claimed combination it was a routine exercise to conduct salt screening to determine that question. Further reasons for this approach were that it was held to be consistent with the approach of the German, Italian and Dutch Courts and that it would apply to variants that rely on, or are based on, developments which occur after the priority date.

Lord Neuberger's reformulated questions also resolve the longstanding issue about when the assessment should be made, thus ending decades of speculation as to what Hoffmann J had meant by "date of publication of the patent" in *Improver*.

Having applied the reformulated questions, the Supreme Court were of the preliminary view that Actavis' products would fall within the scope of protection of the patent as immaterial variants and thus that the DNIs sought should be refused. Nevertheless, it went on to consider whether the prosecution file should lead to a different conclusion.

Prosecution history

Actavis sought to rely on the prosecution history on the basis that the patentee had previously tried to obtain protection for the claimed combination with any pemetrexed compound and that this had been rejected by the EPO on the basis that it introduced subject matter contrary to Article 123(2) EPC. The Supreme Court held that reference to the prosecution file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. Neither situation arose here. Further, although only obiter the Court was of the view that even if the examiner had been right that the wider claim would add subject matter, that consideration did not have any bearing on the question of whether any pemetrexed salts other than pemetrexed disodium should be within the scope of the patent pursuant to the doctrine of equivalents. According to the Court: "*The whole point of the doctrine is that it entitles a patentee to contend that the scope of protection afforded by the patent extends beyond the ambit of its claims as construed according to normal principles of interpretation*".

This has the interesting potential consequence that infringement and validity appear to have become uncoupled in a way that is unfamiliar to the (modern) UK patent practitioner. For example, it may be that infringement and novelty are no longer two sides of the same coin and there is no longer an absolute *Gillette* defence to working the prior art. Equally, it remains to be seen whether breadth of claim sufficiency attacks will need to be measured against the scope of the normally construed claims or against the wider scope of immaterial variants. Of course, the *Kirin-Amgen* approach put paid to these types of questions even if the boundaries of a patent could be fuzzy in certain cases, but it appears that they may have returned. That is not to say that the doctrine of equivalents approach cannot work, as it has been demonstrated to operate in other countries, including the European jurisdictions referred to, without those patent systems falling into disrepute. Nevertheless, it is an interesting thought experiment to imagine whether the Supreme Court would have reached the same conclusion if validity on these types of questions had been in issue.

Infringement in foreign jurisdictions

This part of the judgment will be of particular interest to practitioners in France, Italy and Spain, as the Supreme Court reversed the rulings of the Patents Court and Court of Appeal on infringement in each of those three jurisdictions, notwithstanding that the Court's innovative approach to the doctrine of equivalents only touched upon UK law. The findings in relation to Spain are particularly interesting. Actavis had relied on the argument that Spanish law on construction had been directly modelled on the UK *Improver* case and therefore the Spanish courts would continue to apply the *Improver*/Protocol questions as they were originally stated by Hoffmann J (as he then was in *Improver*) rather than as reformulated by the Supreme Court in the present case, and still find that the Spanish patent was not infringed. The Supreme Court dismissed this argument, holding that as the Spanish courts had followed the previous UK approach judicial comity would tend to suggest that the Spanish courts would now follow the Supreme Court in modifying the Protocol questions even though there was no evidence to this effect.

Indirect infringement

In light of the above, Actavis' cross-appeal on indirect infringement was of little relevance to the outcome and was also highly fact specific. Nevertheless, it is worth noting that the Court dismissed this appeal and that in doing so it made an interesting observation in relation to infringement of Swiss-type medical use claims. In this case Actavis had argued that as the pemetrexed disodium only existed after dissolution of their pemetrexed product in saline by the clinician prior to administration, the pemetrexed disodium formed was part of the medicament but not used in the manufacture of a medicament and thus the Swiss-type claims were not indirectly infringed. The Court dismissed this argument, holding that although the pemetrexed disodium came into the manufacturing process later than it would if the original medicament included pemetrexed disodium rather than a different salt, before the medicament was administered to the patient it included pemetrexed disodium and vitamin B12.

Comment

The process of the Supreme Court re-evaluating UK patent law has previously been described as akin to allowing a group of Vulcan bomber engineers to service a Formula 1 car. This analogy seems to apply to this judgment as well. The implication of the decision, not only in terms of construction and infringement but also validity, will be played out in years to come. But for now, the central dogma of construction in UK patent law: 'what would the skilled person have understood the patentee to have used the language of the claim to mean?' is badly shaken, if not destroyed.